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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284

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EXAMINER	
BROWN, COURTNEY A	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,840	WYNN ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-6, 9-21, and 24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-21 and 24-30* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/04,8/31/05,5/1/06, and 7/1/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Courtney A. Brown.

Acknowledgement of Receipt/Status of Claims

Receipt of Amendments/Remarks filed on August 27, 2008 is acknowledged. Claims 2,7,8,16,22, and 23 stand cancelled. Claims 6,14,2024 and 25 were amended. Claims 27-30 were added. Claims 1, 3-6, 9-21, and 24-30 are pending and are being examined for patentability.

Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on February 11, 2004, August 31, 2005, May 1, 2006, and July 1, 2008 have been considered by the examiner.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application10/697,546.

Copending claim 26 and instant claims 1 and 4 teach the same liquid suspension dosage form comprising: a.) particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming polymer and an enteric

polymer and the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1 and b.) a vehicle for the administration of the particles comprising water or mixtures of water and a pharmaceutically acceptable water-miscible cosolvent selected from the group consisting of glycols, alcohols, and glycerol. The difference between the invention of the instant application and that of copending Application No. 10/697,546 is that the instant application claims a liquid suspension comprising only a controlled release composition as opposed to a liquid suspension comprising a controlled release composition and an immediate release composition. Clemente et al. teach that an extended release formulation can be extremely beneficial at night, so that a child can rest or sleep comfortably for a sufficiently long period of time while under the effects of the analgesic (acetominophen) if the child is in pain, or under the effects of the antipyretic if the child is febrile(column 20, lines 25-36). One would have been motivated to make this combination in order to receive the expected benefit of having pharmaceutically acceptable liquid suspension system that has a therapeutic effect over an extended period of time without exposing the patient such as a child to a large amount of active compound. From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 10/697,546.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As a result, the amount of the controlled release composition covered on the particles of NSAID and/or acetaminophen in the claimed liquid suspension has been rendered indefinite by the use of the term “substantially”.

Claims 1,12,15,17,18,20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the phrase "at least about" in the claims when describing the duration of therapeutic effect for the claimed liquid suspension dosage. It is unclear to the examiner if “at least” or “about” is the intended value.

Claim Objection(s)

The Examiner has observed that claim 1, line 4 states "wherein said controlled release composition is comprises" and should state "wherein said controlled release composition is comprised". Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-21, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US Patent 6,126,969) in view of Singh et al. (US Patent 5,759,579) and Clemente et al (US Patent 6,126,967).

Applicant's Invention

Applicant claims a pharmaceutical liquid suspension dosage form comprising:
a). particles of an NSAID and/or acetaminophen, said particles being substantially covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming polymer and an enteric polymer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1; and
b). a vehicle for the administration of the particles comprising water, wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least about 8 hours after its initial administration to a mammal.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Singh teaches a pharmaceutically acceptable liquid suspension system provided for solid finely divided pharmaceutical actives such as antihistamines, decongestants, antitussives, expectorants, non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetominophen and phenacetin(column 2, lines 30-43). Singh teaches that the aforementioned suspension system comprises water, xanthan gum and hydroxypropyl methylcellulose (abstract). Singh teaches the use of excipients known to the art including humectants such as glycerin and propylene glycol, preservatives such as sodium benzoate and paraben, sweeteners such as sodium saccharin, corn syrup and sorbitol solutions, menthol and various flavoring and coloring agents (column 4,lines 5-9). Singh teaches various examples of liquid suspension systems in columns 4-7 wherein the concentrations of the drug is about 3.2 % and the water content is at least 40%.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the invention of the instant application and that of Singh is that the instant invention claims the use of particles of an NSAID and/or acetaminophen being coated with a controlled release composition as opposed to being uncoated and

used for immediate release. For this reason, the teaching of Shah et al. is joined. Shah et al. teach an orally administrable sustained-release dosage form that includes particles of an active pharmaceutical ingredient which is coated with a polymeric material that is water-insoluble, but water-permeable and water-swellable. Shah et al. teach that the active pharmaceutical ingredient is acetaminophen (abstract) and that the polymer coating can be comprised of one or more polymers (column 4, lines 43-44). Shah et al. teach examples of suitable polymers for use in sustained-release coating of combined immediate-release/sustained-release acetaminophen formulations include: methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxybutylmethyl cellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxymethyl cellulose, cellulose triacetate, cellulose sulphate sodium salt, polymethylmethacrylate, polyethylmethacrylate, polybutymethacrylate, polybutymethacrylate, polyisobutymethacrylate, polyhexomethacrylate, polyisodecylmethacrylate, poly(lauryl methacrylate), poly(phenyl methacrylate), polymethalacrylate, polyisopropylacrylate, polyisbutalacrylate, polyoctadcylacrylate, polyethylene (low or high density), polypropolyne, polyethylene glycol, polyethylene oxide, polyethylene terephthalate, polyvinyl alcohol, polyvinyl isobutyl ether, polyvinyl acetate, polyvinyl chloride and polyvinyl pyrrolidone. Shah et al. teach the examples of suitable copolymers include: butylmethacrylate/isobutylmethacrylate copolymer, high molecular weight, methylvinyl ether/maleic acid copolymer, methlvinyl ether/maleic acid,

monoethyl ester copolymer, methylvinyl ether/malec and anhydride copolymer and vinyl alcohol/vinyl acetate copolymer (column 4, lines 39 bridging to column 5, lines 1-22). Most importantly, Shah et al. teach that the aforementioned orally administrable sustained-release dosage form can be dispersed into water in the form of suspension (column 4, lines 14-17).

Another difference between the invention of the instant application and that of Singh is that the instant invention claims the use of a controlled release composition comprising an insoluble film-forming polymer and an enteric polymer wherein the weight of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1 as opposed to being silent. For this reason, the teaching of Clemente et al. is joined. Clemente et al. teach an extended release composition comprising acetaminophen particles coated with each of a first, second and third layer, the first and third layers being hydroxypropyl cellulose and the second layer being ethylcellulose wherein the weight ratio of each the first, second and third layers on a bead is about 1:4-6:1, respectively(column 4, lines 36-42).

A final difference between the invention of the instant application and that of Singh is that the instant invention claims a pharmaceutical liquid suspension dosage form that has duration of therapeutic effect for at least 8 hours as opposed to being silent. For this reason, the teaching of Clemente et al. is again joined. Clemente et al. teach an extended release acetaminophen composition that provides long term, extended relief in a palatable form wherein the effects of the analgesic is eight or more hours (column 20, lines 25-36).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen being substantially covered with one layer of a controlled release composition. Shah et al. teach an orally administrable sustained-release dosage form and suggests that said sustained-release dosage form can be dispersed into water in the form of suspension (column 4, lines 14-17 of Shah et al.). Clemente et al. teach that an extended release formulation can be extremely beneficial at night, so that a patient such as a child can rest or sleep comfortably for a sufficiently long period of time while under the effects of the analgesic(acetominophen) if the child is in pain, or under the effects of the antipyretic if the child is febrile(column 20, lines 25-36). One would have been motivated to make this combination in order to receive the expected benefit of having pharmaceutically acceptable liquid suspension system that has a therapeutic effect over an extended period of time. Thus, in view of *In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980*), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on August 27, 2008, with respect to the 35 USC 103 (a) rejection of claims 1,3-6,9-15,17-21, and 24-30 have been considered but are moot in view of the new ground(s) of rejection.

None of the claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown
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/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616